K081847

AUG 21 2008

# EXHIBIT 2
## 510(k) Summary

**E-Woo Technology Co., Ltd.**
**1F/4F/5F, Yunmin Technotown, 473-4, Bora-Dong,**
**Giheung-Gu, Yongin-Si, Gyeonggi-Do,**
**Korea 446-904**
**Tel: 82-31-899-7967**
**Fax: 82-31-286-3007**
**Taewoo Kim, President & CEO**
**January 15, 2008**

1. Identification of the Device:
   Proprietary-Trade Name: "Picasso-Master also known as ECT and Master3D"
   Classification Name: System, X-Ray, Tomography, Computed / Product Code JAK
   Common/Usual Name: Computed Tomography X-ray System

2. Equivalent legally marketed device:
   This product is similar in design and identical in function to E-Woo's computed tomography X-ray system Model EPX-Impla (K070658, E-Woo Technology Co., Ltd.), Extraoral Source X-ray System, Model i-CAT Scanner (K061284, Imaging Science International Inc.)

3. Indications for Use (intended use):
   "Picasso-Master also known as ECT and Master3D" is a computed tomography x-ray system intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. It provides diagnostic details of the anatomic structures for surgical planning of oral and maxillofacial area by acquiring 360° rotational image sequences of the head and neck areas, including the ENT and dentomaxillofacial area. The device is operated and used by physicians, dentists, and x-ray technicians.

4. Description of the device:
   "Picasso-Master also known as ECT and Master3D" is equipped with state-of-the-art CMOS-CT sensor to capture 3D x-ray computerized tomography scanned image. It is capable of real time-image acquisition through an advanced digital imaging process which allows considerably efficient diagnosis, information management, and real-time sharing of image information on network.

5. Safety and Effectiveness, comparison to predicate device

| Feature | Predicate: (I-CAT Scanner, K061284) | Predicate: Dental Imaging System (EPX-Impla, K070658) | New Device "Picasso-Master, ECT, Master3D" |
|---|---|---|---|
| Manufacturer | Imaging Sciences International Inc. USA | E-Woo Technology Co., Ltd. Korea | E-Woo Technology Co., Ltd. Korea |
| Intended Use | The Imaging Sciences International Inc. i-CAT Scanner constructs a three dimensional model from images taken during a rotational X-ray sequence. The Imaging Sciences i-CAT Scanner is intended to be used whenever a dentist, oral surgeon, or other physician needs 3D information of high contrast objects. The system is designed for imaging of | EPX-Impla is intended to be used for three Dimensional imaging for dental Purposes. Provides details of the anatomic structures for oral and maxillofacial surgical procedures. | "Picasso-Master, ECT, Master3D" is a computed tomography x-ray system intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from |

| | | | |
|---|---|---|---|
| | TM Joint studies, mandible & maxilla for implant planning, sinuses, and other areas of the maxillofacial complex. | | the same axial plane taken at different angles. It provides diagnostic details of the anatomic structures for oral and maxillofacial surgical treatment. |
| Indication for Use | The i-CAT Scanner is a dedicated X-Ray imaging device that acquires a 360o rotational X-ray sequence, reconstructs a three-dimensional matrix of the examined volume and produces two dimensional views of this volume. The i-CAT Scanner can measure distances and thickness on two dimensional images. Images produced by the i-CAT Scanner can be printed or exported on magnetic and optical media. | EPX-Impla is a computed tomography x-ray system that acquires a 360° rotational sequence of the head and neck areas, including the ENT and dentomaxillofacial area for use in diagnostic support. The device is operated and used by physicians, dentists, and x-ray technologists. | "Picasso-Master, AKA ECT, Master3D"acquires a 360° rotational sequence of the head and neck areas, including the ENT and dentomaxillofacial area for use in diagnostic support. The device is operated and used by physicians, dentists, and x-ray technicians. |
| X-ray Beam | Cone | Cone | Cone |
| Detector | Flat-Panel Detector (Amorphous Silicon) | Flat-Panel Detector (CsI + Photo Diode) | Flat-Panel Detector (CsI + Photo Diode) |
| Grayscale | 14 | 12 | 12 |
| Voxel size (㎣) | 0.2-0.4 | 0.2 | 0.2 |
| Number of Voxel | 275 x 425 | 416 x 416 | 224 × 224 × 160 (20X15)<br>352 × 352 × 256 (20X15)<br>608 × 608 × 448 (20X15) |
| Rotation angle | 360 degree | 360 degree | 360 degree |
| Scan time (sec) | 10, 20 (standard), 40 | 15 | 24 |
| Pateint position | Seated | Stand | Seated |
| FOV(3) (cm x cm) | 17 x 13<br>16 x 22 (Optinal Extended FOV) | 12 x 7<br>8 x 5 | 20 x 15<br>20 x 19 |
| Reconstruction time | 1.5min (20 sec scan) | Less than 2 min | 3min |
| KVp range | 120 | 40~90(Normal 85kV) | 50~90(Normal 85kV) |
| mA range | 3-8 (Pulse mode) | 2~10(Normal 7) | 2~10(Normal 7) |
| Focal spot (mm) | 0.5 | 0.4 | 0.4 |
| CT Slice Thickness | 0.800~0.200 mm | 0.1~1.0mm | 0.1~1.0mm |

6. Testing information and Conclusion

In all material respects, the "Picasso-Master also known as ECT and Master3D" is substantially equivalent to Dental Imaging System EPX-Impla,(K070658, E-Woo Technology Co., Ltd.). Testing was performed according to internal company procedures. Software testing and validation were done according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to release. Test results support the conclusion that actual device performance satisfies the design intent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 2008

E-Woo Technology Company, Ltd.
% Mr. Tamas Borsai
Responsible Third Party Official
TÜV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K081847
Trade/Device Name: Picasso-Master also known as ECT and Master 3D
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: August 13, 2008
Received: August 14, 2008

Dear Mr. Borsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known) :

Device Name : "Picasso-Master, also known as ECT and Master3D"

Indications For Use : "Picasso-Master also known as ECT and Master3D" is a computed tomography x-ray system intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. It provides diagnostic details of the anatomic structures for surgical planning of oral and maxillofacial area by acquiring 360° rotational image sequences of the head and neck areas, including the ENT and dentomaxillofacial area. The device is operated and used by physicians, dentists, and x-ray technicians.

Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081847